



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m9218n

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

February 28, 2001

via Federal Express

MQSA Facility ID: 196824
Inspection ID: 1968240006

FDA Reference #: 2952203

C. Allen Wall, M.D.
The Wall Medical Group, Coastside Radiology
455 Grand Avenue
South San Francisco, CA 94080

Dear C. Allen Wall M.D.,

We are writing to you because on February 20, 2001, a representative of the State of California, acting in behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

- Level 1: The system to communicate results is not adequate for site The Wall Medical Group, Coastside Radiology because:
 - There is no system in place to provide timely medical reports
 - There is no system in place to provide timely lay summaries
 - There is no system in place to communicate serious or highly suggestive cases as soon as possible.
- Level 1: Processor QC records were missing 2 out of 2 days of operation in month 01/2001. Processor QC records missing 100%, for processor 1, [REDACTED] room Main at site The Wall Medical Group, Coastside Radiology

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: There is no written procedure for handling consumer complaints at site The Wall Medical Group, Coastside Radiology
- Level 2: Processor QC records were missing 2 consecutive days for processor 1, [REDACTED] room Main at site The Wall Medical Group, Coastside Radiology
- Level 2: The measured fog density is equal to 0.13 for darkroom Main at site The Wall Medical Group, Coastside Radiology
- Level 2: Phantom QC records were missing for at least two weeks but less than four weeks for unit 1, [REDACTED] room Mammography
- Level 2: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 1, [REDACTED] room Mammography

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

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- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

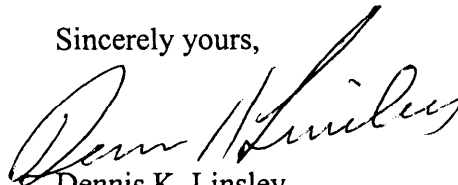
Please submit your response to:

Russell A. Campbell, Compliance Officer
San Francisco District
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell A. Campbell at 510-337-6861.

Sincerely yours,



Dennis K. Linsley
District Director

**This note is not applicable for letters which also address patient notification*